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| 10/070,318      | 08/09/2002  | Stephen James Brocchini | G0365.0352/P352     | 4587             |

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New York, NY 10036-2714

| EXAMINER |
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PEZZUTO, HELEN LEE

| ART UNIT | PAPER NUMBER |
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1713

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/070,318

**Applicant(s)**

BROCCHINI ET AL.

**Examiner**

Helen L. Pezzuto

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☒ Claim(s) 16-21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

Applicant's amendment to claims 3-8, 10-11, 13, 17, 24-30, and 34-37 filed in the preliminary amendment on 3/5/02 is acknowledged. Currently, claims 1-37 are pending in this application.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 15, 22, 31 and claims dependent thereon are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow

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language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the recitation of "preferably" and "most preferably" throughout the pending claims embodies the broad recitation and the narrower statement of the range/limitation.

4. Claim 37 provides for the use of the polymer as an excipient, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 37 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

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USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*,  
255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferruti et al. (US-152).

U.S. 4,228,152 to Ferruti et al. discloses polymers having a molecular weight between 1,000 and 1,500,000, containing prostaglandin radicals directly connected through an oxyalkylenic, aminoalkylenic, or oxyaminoalkylenic chain to a poly(meth)acrylic backbone. Prior art acrylic monomer contains reactive groups, including those of presently claimed (i.e. N-acrylosuccinimide, 1-acrylsimidazole) (col. 3, line 21 to col. 4, line 41; col. 8, polymers V and VI; claims 1, 8, and 13).

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7. Claims 1, 15, 22, 31 and claims dependent thereon are rejected under 35 U.S.C. 103(a) as being unpatentable over Erout et al. (Polymer (1996), 37(7), 1157-65.

The article to Erout et al. is directed to kinetic and microstructure studies of free radical-initiated copolymers of N-vinylpyrrolidone and N-acryloxy succinimide. Prior art discussed the utility of these activated esters in reacting with biomolecules containing primary amine groups which fall within the scope of the processes expressed in claims 22, and 31. Homopolymerization of N-acryloxy succinimide was also disclosed which embraces the instant claim 15.

8. Claims 1, 15 and claims dependent thereon are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (J. Controlled Release (1997), 45(1), 95-101.

Prior art is related to hydrolysis kinetic studies of polymer-drug conjugates, specifically copolymers of n-isopropyl acrylamide and N-acryloxy succinimide. Homopolymerization of N-acryloxy succinimide and its subsequent copolymerization with N-isopropyl acrylamide were investigated which encompass the scope of the instant claims 1 and 15.

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9. Claims 1, 15 and claims dependent thereon are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (Eur. Polym J. (1988)).

Prior art is directed to radiation-induced polymerization of (meth)acrylic esters of N-hydroxysuccinimide. Prior art further discussed coupling of enzymes, antibodies/antigens and drugs to functionalized N-hydroxysuccinimide-containing polymers in their introductory section.

10. Claims 1, 22, 31 and claims dependent thereon are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (ACS Symposium Series (1987), 350, 245-54) or Yang et al. (J. Polym. Sci. (1990), 28(1), 219-26).

The article to Cole et al discloses a free-radical process of producing N-isopropylacrylamide and N-acryloxysuccinimide copolymers and the subsequent reaction of the activated copolymer with immunoglobulin. It would be reasonable to one skilled in the art to assume that proteins would inherently possess HR\* groups which are reactive to the acryl groups on the copolymer.

Similarly, Yang et al. disclose the preparation of N-isopropylacrylamide and N-acryloxysuccinimide

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copolymer and studied the control of active ester groups in the polymer as related to its subsequent coupling to binding ligands such as antibodies and other proteins. The number average molecular weight and polydispersity of the resulting copolymer as well as their experimental controls were also discussed.

All prior art references discussed in the preceding paragraphs are related to copolymer containing active acyl groups capable of binding to a variety of biological molecules such as proteins, as well as drugs. The presently claimed polymer as broadly represented by unit (1) clearly fall within the scope of prior art activated copolymer with the same utility. Some of the prior art references are silent regarding the recited polydispersity and molecular weight. The examiner is of the position that one skilled in the art would envisage the claimed Mw and polydispersity under the general conditions of prior art disclosures because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.



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***Allowable Subject Matter***

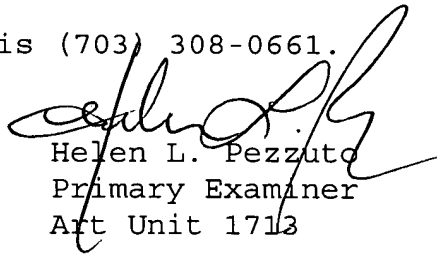
11. Claims 16-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Prior art of record disclose free radical copolymerization of the instant polymer, but do not disclose the specific process mechanism as recited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen L. Pezzuto whose telephone number is (703) 308-2393. The examiner can normally be reached on 8 AM to 4 PM, Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (703) 308-2450. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
Helen L. Pezzuto  
Primary Examiner  
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